

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

**WHAT IS CLAIMED IS:**

1. A medical device having on a surface thereof a bio-compatible coating, said bio-compatible coating formed from a composition comprising an aqueous emulsion or dispersion of a polycarbonate-polyurethane composition containing one or more internal emulsifying agents.
2. The medical device of claim 1, wherein said one or more internal emulsifying agents comprise one or more organic acid functional groups selected from the group consisting of free carboxylic acid, free sulfonic acid, free phosphoric acid and combinations thereof.
3. The medical device of claim 2, wherein said bio-compatible coating further comprises an excess of a polyfunctional cross-linking agent which is reactive with said one or more organic acid functional groups on said polycarbonate-polyurethane composition.
4. The medical device of claim 3, wherein said polyfunctional cross-linking agent is selected from the group consisting of polyfunctional aziridines, polyfunctional carbodiimides and mixtures thereof.
5. The medical device of claim 4, wherein said bio-compatible coating further contains a second coating composition which comprises a bio-active agent having one or more organic acid functional groups which are covalently reactive with said excess polyfunctional cross-linking agent.
6. The medical device of claim 5, wherein said bio-active agent is selected from the group consisting of thrombo-resistant agents, antibiotic agents, anti-tumor agents, growth hormones, antiviral agents, anti-angiogenic agents, angiogenic agents, anti-mitotic agents, anti-inflammatory agents, cell cycle regulating agents, genetic agents, hormones, their homologs, derivatives, fragments, pharmaceutical salts and combinations thereof.

7. The medical device of claim 6, wherein said bio-active agent is selected from the group of thrombo-resistant agents consisting of heparin, heparin sulfate, hirudin, hyaluronic acid, chondroitin sulfate, dermatan sulfate, keratan sulfate, lytic agents, including urokinase and streptokinase their homologs, analogs, fragments, derivatives and pharmaceutical salts thereof.

5  
8. The medical device of claim 6, wherein said bio-active agent is selected from the group of antibiotic agents consisting of penicillins, cephalosporins, vancomycins, aminoglycosides, quinolones, polymyxins, erythromycins, tetracyclines, chloramphenicols, clindamycins, lincomycins, sulfonamides their homologs, analogs, derivatives, pharmaceutical salts and  
10 mixtures thereof.

9. The medical device of claim 6, wherein said bio-active agent is selected from the group of anti-tumor agents consisting of paclitaxel, docetaxel, alkylating agents including mechlorethamine, chlorambucil, cyclophosphamide, melphalan and ifosfamide; antimetabolites  
15 including methotrexate, 6-mercaptopurine, 5-fluorouracil and cytarabine; plant alkaloids including vinblastine, vincristine and etoposide; antibiotics including doxorubicin, daunomycin, bleomycin, and mitomycin; nitrosureas including carmustine and lomustine; inorganic ions including cisplatin; biological response modifiers including interferon; angiostatin agents and endostatin agents; enzymes including asparaginase; and hormones including tamoxifen and  
20 flutamide their homologs, analogs, fragments, derivatives, pharmaceutical salts and mixtures thereof.

10. The medical device of claim 6, wherein said bio-active agent is selected from the group of anti-viral agents consisting of amantadines, rimantadines, ribavirins, idoxuridines,  
25 vidarabines, trifluridines, acyclovirs, ganciclovirs, zidovudines, foscarnets, interferons their homologs, analogs, fragments, derivatives, pharmaceutical salts and mixtures thereof.

11. The medical device of claim 1, wherein the concentration of said aqueous emulsion or dispersion is from about 1% to about 50% by weight solids content.

12. The medical device of claim 1, wherein said substrate is a polymer, a non-polymer and combinations thereof.

13. The medical device of claim 12, wherein said polymer is selected from the group consisting of degradable polymers, non-degradable polymers and mixtures thereof.

14. The medical device of claim 13, wherein said substrate is further selected from the group of polymer compositions consisting of olefin polymers including polyethylene, polypropylene, polyvinyl chloride, polytetrafluoroethylene, polyvinyl acetate, polystyrene, poly(ethylene terephthalate), polyurethane, polyurea, silicone rubbers, polyamides, polycarbonates, polyaldehydes, natural rubbers, polyether-ester copolymers, styrene-butadiene copolymers and combinations thereof.

15. The medical device of claim 13, wherein said substrate is further selected from the group of polymer compositions consisting of polysaccharides such as for example, methyl cellulose, hydroxymethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, hydroxypropylethyl cellulose, sodium carboxymethyl cellulose, hyaluronic acid, chondroitin sulfate, chitosan, dextran, xanthan, gellan, alginic acid, jeta carrageenan; polypeptides such as for example, collagen, gelatin, elastin, albumin; and synthetic polymers such as for example, poly(vinyl alcohol), poly(lactic acid), polyglycolic acid, poly-ε-caprolactone, polyanhydride their copolymers and mixtures thereof.

16. The medical device of claim 12, wherein said substrate is further selected from the group of non-polymer compositions consisting of ceramics, metals, glasses and combinations thereof.

17. The medical device of claim 16, wherein said substrate is further selected from the group of metals consisting of stainless steel, nitinol, tantalum, titanium, gold, silver, their alloys and mixtures thereof.

18. The medical device of claim 1, wherein said substrate is an implantable device.

19. The medical device of claim 18, wherein said implantable device is selected from the group consisting of grafts, stents, graft-stent combinations and catheters.

5

20. The medical device of claim 19, wherein said stents are selected from the group consisting of vascular and nonvascular stents.

10

21. The medical device of claim 20, wherein said nonvascular stents are selected from the group consisting of esophageal, urinary, biliary and colonic stents.

22. A process for rendering a medical device bio-compatible comprising:

15

- a) providing a substrate with a coating comprising an aqueous emulsion or dispersion of a polycarbonate-polyurethane composition having at least one internal emulsifying agent; and
- b) drying said coating onto said substrate to attach said coating to said substrate.

20

23. The process of claim 22, wherein said at least one internal emulsifier is at least one organic acid functional group.

24. The process of claim 23, wherein said coating further comprises an excess of a polyfunctional cross-linking agent which is reactive with said at least one organic acid functional group on said polycarbonate-polyurethane composition.

25. The process of claim 24, further comprising the steps of:

- a. contacting said substrate having said dried coating thereon with a bio-active agent, and
- b. forming a continuous bio-active coating on a surface of said substrate by drying said bio-active agent to covalently bond said bio-active agent to said coating via said excess polyfunctional cross-linking agent.

26. A coating for enhancing the bio-activity of a surface of a medical device, said coating formed from an aqueous emulsion or dispersion comprising a polycarbonate-polyurethane composition containing an organic acid functional group and an excess of a polyfunctional cross-linking agent, said composition forming a coating on a surface of said medical device and being bonded thereto and reactive with bio-active agents.

27. A medical device with enhanced thrombo-resistance comprising:

- a) a substrate having a surface to which a continuous thrombo-resistant coating may be attached; and
- b) a thrombo-resistant coating that contains an aqueous emulsion or dispersion of a polycarbonate-polyurethane composition containing an internal emulsifying agent, said composition being attached to said substrate surface.

28. The medical device of claim 27, wherein said polycarbonate-polyurethane composition is prepared by reacting a polyfunctional isocyanate with a polycarbonate diol.

29. A medical device having a surface rendered bio-compatible by means of a first coating layer, said first coating layer comprising a polycarbonate-polyurethane composition containing an internal emulsifying agent.

30. The device of claim 29, wherein said internal emulsifying agent includes at least one organic acid functional group.

31. The device of claim 30, wherein said composition further comprises a polyfunctional cross-linking agent.

32. The device of claim 31 further comprising a second coating layer of a bio-active agent covalently bonded to said first coating layer, said second coating formed by the process of

a) drying said first coating layer to said medical device;

b) applying an aqueous emulsion or dispersion of said bio-active agent having at least one organic acid functional group onto said dried first layer;

c) drying said first and second layers to covalently bond said first layer to said second layer via said organic acid functional group on said second layer and said multifunctional cross-linking agent.

33. A medical device having a surface coated with a bio-active layer comprising the reaction product of a polycarbonate-polyurethane first layer containing an internal emulsifying agent and a polyfunctional cross-linking agent and a bio-active agent second layer having at least one organic acid functional group.